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Colleen Lombard

Printed name of person mailing correspondence

Colleen Lombard

Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Eggert Stockfleth

Confirmation No.: 7550

Serial No.: 10/574,422

Art Unit:

Filed: April 4, 2006

Examiner:

Customer No.: 21559

Title: THE USE OF A POLYPHENOL FOR THE TREATMENT OF A
CANCEROUS OR PRE-CANCEROUS LESION OF THE SKIN

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SUBMISSION OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Applicant submits herewith the International Preliminary Examination Report corresponding to the above-referenced application. Applicants petition for any necessary extensions of time for submission of this document.

In addition, if there are any charges, or any credits, please apply them to Deposit
Account No. 03-2095.

Respectfully submitted,

Date: 20 June 2006


Karen L. Elbing, Ph.D.

Reg. No. 35,238

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

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From the INTERNATIONAL BUREAU

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NOTIFICATION CONCERNING
 TRANSMITTAL OF COPY OF INTERNATIONAL
 PRELIMINARY REPORT ON PATENTABILITY
 (CHAPTER I OF THE PATENT COOPERATION
 TREATY)
 (PCT Rule 44bis.1(c))

Date of mailing (day/month/year)
 20 April 2006 (20.04.2006)

To:

BÖSL, Raphael
 Isenbruck Bösl Hörschler Wichmann Huhn
 Prinzregentenstrasse 68
 81675 München
 ALLEMAGNE

Applicant's or agent's file reference
 M62438PC

IMPORTANT NOTICE

International application No.
 PCT/EP2004/011300

International filing date (day/month/year)
 08 October 2004 (08.10.2004)

Priority date (day/month/year)
 09 October 2003 (09.10.2003)

Applicant

MEDIGENE AG et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

Isenbruck Bösl Hörschler Wichmann Huhn, Patentanwälte Postfach 860 880 D-81635 München	
26. April 2006	
Frist: 09.05.06 PCT-B1	
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The International Bureau of WIPO
 34, chemin des Colombettes
 1211 Geneva 20, Switzerland

Authorized officer

Ellen Moyse

Facsimile No.+41 22 740 14 35

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference M62438PC	FOR FURTHER ACTION		See item 4 below		
International application No. PCT/EP2004/011300	International filing date (<i>day/month/year</i>) 08 October 2004 (08.10.2004)		Priority date (<i>day/month/year</i>) 09 October 2003 (09.10.2003)		
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237					
Applicant MEDIGENE AG					

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p>	<p>Date of issuance of this report 10 April 2006 (10.04.2006)</p>
<p>Facsimile No. +41 22 740 14 35</p>	<p>Authorized officer Ellen Moyse Telephone No. +41 22 338 89 75</p>

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/011300

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	30-34
	No: Claims	1-29,35
Inventive step (IS)	Yes: Claims	
	No: Claims	1-35
Industrial applicability (IA)	Yes: Claims	1-35
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)
and / or
2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Section V

1. Reference is made to the following documents:

D1: WO 2004/026323 A (BARROS, SILVIA, BERLANGA, DE, MORAES; FUNDACAO DE AMPARO A PESQUISA DO) 1 April 2004 (2004-04-01)

D2: ZHU A ET AL: "Study of tea polyphenol as a reversal agent for carcinoma cell lines' multidrug resistance (study of TP as a MDR reversal agent)" NUCLEAR MEDICINE AND BIOLOGY, ELSEVIER SCIENCE PUBLISHERS, NEW YORK, NY, US, vol. 28, no. 6, August 2001 (2001-08), pages 735-740, XP004301003 ISSN: 0969-8051

D3: WO 2004/053097 A (MEDICAL COLLEGE OF GEORGIA RESEARCH INSTITUTE, INC; HSU, STEPHEN; SCHU) 24 June 2004 (2004-06-24)

D4: PRONIUK S ET AL: "Preformulation study of epigallocatechin gallate, a promising antioxidant for topical skin cancer prevention" JOURNAL OF PHARMACEUTICAL SCIENCES, AMERICAN PHARMACEUTICAL ASSOCIATION. WASHINGTON, US, vol. 91, no. 1, January 2002 (2002-01), pages 111-116, XP002270297 ISSN: 0022-3549

D5: MUKHTAR H ET AL: "GREEN TEA POLYPHENOLS INDUCE APOPTOSIS AND ALTER THE PROGRESSION OF CELL CYCLE IN HUMAN EPIDERMOID CARCINOMA CELLS A431" PROCEEDINGS OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH AND AMERICAN SOCIETY OF CLINICAL ONCOLOGY, XX, XX, vol. 38, March 1997 (1997-03), page 580, XP000997348

D6: LINDEN K ET AL: "Chemoprevention of non-melanoma skin cancer: Experience with a polyphenol from green tea" EUROPEAN JOURNAL OF CANCER, PERGAMON PRESS, OXFORD, GB, vol. 38, February 2002 (2002-02), page S24, XP004367780 ISSN: 0959-8049

D7: WO 01/51048 A (COLOR ACCESS, INC) 19 July 2001 (2001-07-19)

D8: MCCARTY M F: "POLYPHENOL-MEDIATED INHIBITION OF AP-1 TRANSACTIVATING ACTIVITY MAYSLOW CANCER GROWTH BY IMPEDING ANGIOGENESIS AND TUMOR INVASIVENESS" MEDICAL HYPOTHESES, EDEN PRESS, PENRITH, US, vol. 50, June 1998 (1998-06), pages 511-514, XP000957651 ISSN: 0306-9877

D9: CAO Y ET AL: "ANGIOGENESIS INHIBITED BY DRINKING TEA" NATURE,

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/011300

MACMILLAN JOURNALS LTD. LONDON, GB, vol. 398, 1 April 1999 (1999-04-01), page 381, XP000953295 ISSN: 0028-0836

D10: US 2003/166583 A1 (YOA-PU HU OLIVER ET AL) 4 September 2003 (2003-09-04)

2. It is already known from the prior art that polyphenols isolated from e.g. green tea, especially derivatives of catechin (or catechol) can be used in the treatment and prevention of different skin disorders, especially skin cancer (cf. D2 and D4 to D10; parts indicated in the search report). The subject-matter of present claims 1 to 29 and 35 therefore lacks the necessary novelty over the prior art and the requirements of Article 33 (2) PCT have not been fulfilled.
3. Since the effect of polyphenols isolated from green tea on cancerous cells is known, it cannot be considered inventive to combine it with other already known agents used for the same indication, especially since no surprising or unexpected effect has been shown. The requirements of Article 33 (3) EPC have therefore not been fulfilled for claims 1-35.

Section VI

Certain documents cited

Certain published documents

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO2004/026323	01/04/04	17/09/03	18/09/02
WO2004/053097	24/06/04	10/12/03	10/12/02

Section VIII

Certain observations on the international application

The subject-matter of claims 21-26 disclose certain amounts of polyphenols. It is unclear whether these amounts are relative to the complete compositions or relative

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/011300

the other active ingredients.